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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/810,101	03/25/2004	Gregor Sagner	022101-001910US	8546

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EXAMINER	
CHUNDURU, SURYAPRABHA	
ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 09/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	10/810,101	SAGNER ET AL.	
	Examiner	Art Unit	
	Suryaprabha Chunduru	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/25/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status

1. Claims 1-6 are cancelled by the Preliminary Amendment filed on March 25, 2004. Claims 7-14 are pending and are considered for examination in this office action.

Priority

2. This application filed on March 25, 2004 is a CON of US non-provisional 09/823,712 filed on 3/30/2001which claims benefit of foreign application EPO 00 107 036.6 filed on 3/31/2000, GERMANY 100 34 209.4 filed on 7/13/2000, and GERMANY 100 45 521.2 filed on 9/13/2000.

Information Disclosure Statement

3. The Information Disclosure Statement filed on March 25, 2004 has been considered.

Objection to the specification

4. The disclosure is objected to because of the following informalities:

The use of the trademark 'Taqman' has been noted in this application (see page 15, (ii)). It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks. Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 recites "the two quotients from step h)" in line 1 of step (i) of the claim. The meets and bounds of the claim is unclear and indefinite because the step h), upon which the limitation depends recite ' calculating the quotients of the function values from step g) of the target nucleic acid and reference nucleic acid for the sample to be analyzed *as well as* for the calibrator sample' which indicates calculating three quotients, that is, for target nucleic acid, reference nucleic acid and a the calibrator sample. Thus the limitation reciting 'the two' is unclear and indefinite as it is not clear to what two quotients it represents out of the three calculated quotients.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lowe et al. (WO 99/54510) in view of Wittwer et al. (USPN. 6,174,670).

Lowe et al. teach a method of claim 9 for determining a quantitative measure of an amplification of a target nucleic acid comprising the steps of

(a) preparing a dilution series of the target nucleic acid and reference nucleic acid (see page 3, line 12-14, page 6, line 20-28, page 11, line 24-35, page 13, line 30-39, page 14, line 1-19);

(b) amplifying the target and reference nucleic acid under defined conditions and measuring the amplification in real-time (see page 3, line 14-25, page 13, line 30-39, page 14, line 1-19);

(c, d) setting a defined signal threshold value and determining for each dilution, the cycle number at which the signal threshold value is exceeded (threshold cycle for each dilution) (see page 3, line 25-27, page 10, line 16-23);

(f) calculating the amplification equivalent in each dilution series and normalizing the RNA equivalent to provide normalized RNA equivalent standard curve. (see page 3, line 29-33, page 10, lines 31-39).

With regard to claim 9, Lowe et al. teach determining concentration of the target nucleic acid (see page 12, line 9-15);

With regard to claim 9, Lowe et al. also teach quantifying the amount of target nucleic acid relative to the reference nucleic acid (see page 13, line 30-39, page 14, line 1-19);

quantitation of a target nucleic acid using internal standard or reference nucleic acid (see page 13, line 10-39).

However, Lowe et al. did not teach determining a continuously differentiable function of a logarithm of copy number.

Wittwer et al. teach a method of claims 9, for monitoring and quantitating target nucleic acid during real- PCR, wherein Wittwer et al. disclose that the method DNA monitoring at each PCR cycle by measuring melting curves and calculating copy number at each cycle utilizing DNA-binding dye (SYBR Green I), which represents a continuously differentiable function of logarithm of copy number that is represented as a polynomial fit of copy number of target nucleic acid at each PCR cycle (see col. 3, line 30-61, col. 4, line 45-63, col. 7, line 14-31, Fig. 22-23, Col. 17, line 34-39).

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made, to combine a method of determining the efficiency of amplification and quantitating a target nucleic acid as taught by Lowe et al. in view of Wittwer et al. with the step of monitoring nucleic acid amplifcation as taught by Wittwer et al. to achieve expected advantage of developing an improved sensitive method for quantitating a target nucleic acid because Wittwer et al. explicitly taught that the correlation between the threshold cycle and the initial concentration of DNA templates copy number provides precise measurement of abundance of target nucleic acids and its linear functionality (see col. 4, line 45-63). An ordinary practitioner would have been motivated to combine the method of determining the efficiency of an amplification of a target nucleic acid and quantitation of said nucleic acid as taught by Lowe et al. with the inclusion of monitoring continuously differentiable function of logarithm of copy

number as taught by Wittwer et al. because an ordinary practitioner would have a reasonable expectation of success that the combination would result in enhancing the sensitivity of the method for quantitation of a target nucleic acid and such modification of the method is considered obvious over the cited prior art in the absence of secondary consideration.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 7-8, 10-14 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 31-41 of copending Application 09/823,712 (Pub No. US 2002/0058262A1). Although the conflicting claims are not identical, they are not patentably distinct from each other because An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed.Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed.Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other

because the claims 7-8, and 10 are generic to all that is recited in claims 31, 38-39 of the co-pending application. That is, the claims 31, 38-39 of the co-pending application fall entirely within the scope of claims 7-8, 10 or in other words, claims 7-8 and 10 are anticipated by the claims 31, 38-39 of the co-pending application. Specifically the method of steps (a) through (d) disclosing a method for absolute quantitation of a target nucleic acid relative to a reference nucleic acid comprising are within the scope of the claims 31, 38-39 of the co-pending application. Further the instant claims 11 is generic to all that is recited in the claims 32-33 of the co-pending application, claims 12-14 are generic to all that is recited in claims 34-37 of the co-pending application. Thus the instant claims encompass the claims in the co-pending application and are related as genus and species, and are coextensive in scope.

The courts have stated that a genus is obvious in view of the teachings of a species. see Slayter, 276 F.2d 408, 411, 125 USPQ 345, 347 (CCPA 1960); and In re Gosteli, 872 F.2d 1008, 10 USPQ2d 1614 (Fed.Cir. 1989). Therefore the instantly claimed method preparing cell lysate is obvious over the claims in the co-pending.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M , Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Suryaprabha Chunduru
Primary Examiner
Art Unit 1637

Prabha Chunduru
SURYAPRABHA CHUNDURU
PATENT EXAMINER
9/21/06